10

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,615	02/28/2002	Motoo Yamasaki	249-159	4132

23117 7590 07/22/2004

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
BORIN, MICHAEL L	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/084,615	YAMASAKI ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-33* is/are pending in the application.

4a) Of the above claim(s) *15-23,25-27 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/696,988.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5 IDSs*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 15-33 are pending.

2. Response to restriction requirement filed 05/20/2004 is acknowledged. Applicant elected, without traverse, Group III, claims 24-33. Claims 15-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 15-23 is requested.

As per election of species, applicant elected structure of SEQ ID No.1 (as in claim 24b), having no substitutions. Claims 25-27, drawn to non-elected species are withdrawn from consideration. Also, applicant elected polyalkylene species of claim 29(a) that modify amino group of SEQ ID No. 1. Claims 30-32, drawn to non-elected species are withdrawn from consideration.

Claims 24,27,28 are under examination.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24,28,29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is the objective of the method. Claim 24 recites the patient to be treated but not the effect to be achieved.

Claim Rejections - 35 USC § 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 24,28,29 are rejected under 35 U.S.C. 102(e) as anticipated by Ishikawa et al. (US 5,824,778).

The instant claims are drawn to method of treatment of patients with decreased platelet counts using hG-CSF modified with a polyalkylene glycol derivative.

Ishikawa et al. (US 5,824,778) teach that human G-CSF is one of the hematopoietic growth factors useful in the treatment of general hematopoietic disorders. For the purpose of decreasing the clearance rate, improving stability or abolishing antigenicity, proteins are chemically modified by using polyethylene glycol. Ishikawa et al. teach polyethylene glycol-modified human G-CSF which has a more

enduring pharmacological effect, which may be possibly attributed to its prolonged half-life in body. Any purified and isolated natural or recombinant human G-CSF can be modified by polyethylene glycol; in particular the reference describes hG-CSF of instant SEQ ID No. 1 (see abstract). The modified hG-CSF has an activity for increasing the number of neutrophils, and it is therefore useful in the treatment of general hematopoietic disorders including those arising from chemotherapy or from radiation therapy. It may be also useful in the treatment of infection and under receiving the therapy of bone marrow transplantation. See col. 4, lines 22-31. As patients with disorders arising from chemotherapy or from radiation therapy or receiving therapy of bone marrow transplantation suffer from decreased platelet count, the reference is viewed as teaching method of treatment of patients with decreased platelet counts using hG-CSF modified with a polyalkylene glycol derivative.

5. Claims 24,28,29 are rejected under 35 U.S.C. 103(a) as obvious over Background art or Tanikawa or WO 91/07988 or Koike et al, or Washizuka et al, and in view of Ono et al (US Patent 5,342,940) or Ishikawa et al. (US 5,824,778).

Background section informs that prior art teaches that hG-CSF is one of the polypeptides essential for hemopoietic stem cell growth and differentiation leading to

the formation of various types of hemocytes, and exerts growth-promoting effect on most granulocytes and in particular neutrophils. Further, Tanikawa or WO 91/07988 or Koike et al, or Washizuka et al (references submitted by applicant) teach use of hG-CSF in treatment of patients with hematopoietic injuries. In particular, the latter two references emphasize that administration of hG-CSF triggers increase in platelets.

Both Ono et al (US Patent 5,342,940) and Ishikawa et al. (US 5,824,778) teach that proteins, hG-CSF in particular, can be chemically modified by using polyethylene glycol for the purpose of decreasing the clearance rate, improving stability or abolishing antigenicity.

Thus, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to be motivated to modify hG-CSF with a polyethylene glycol derivative to improve its pharmacological properties and to use thus modified hG-CSF to treat hematopoietic injuries in, for example, patients suffering from decreased platelet count.

Conclusion.

6. No claims are allowed

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-

0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

July 20, 2004

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER